

## REMARKS

### *Status of the Claims*

Claims 1-16 are pending. Claims 1, 3 and 10-16 have been amended. Claim 2 has been canceled. Claims 17-22 are new.

Claims 1 and 3 have been amended to remove the word “derivative”. Additionally, some minor grammatically corrections have also been made to claims 1 and 3.

Claim 10 has been amended to remove the preferred and particular ranges for the active substances, the binder and the excipients. The preferred and particular ranges for the active substances, binder and excipients have been included in new claims 17 and 18.

Claim 11 has been amended to remove the preferred and particular ranges for the enteric binder. The preferred and particular range for the enteric binder have been included in new claims 19 and 20.

Claim 12 has been amended to remove the preferred and particular ranges for the active substances. The preferred and particular ranges for the active substances have been included in new claims 21 and 22.

In view of the amendments to claim 1, claim 13 has been amended to remove the reference to fenofibric acid and fenofibrate. Additionally, claim 13 has also been amended to make the claim more clear and to conform the claim to U.S. practice (namely, by removing the “e.g. highly disperse silica gel” language).

In view of the amendments to claim 1, claims 14 and 15 have been amended to remove the word “derivative”. In addition, minor grammatical and spelling corrections have also been made to claims 14 and 15.

Claim 16 has been amended to make this claim read more clearly by inserting “A” in front of “dosage form”.

New claims 17-22 were discussed above.

Applicants submit that neither the amendments to claims 1, 3 and 10-16 nor the addition of claims 17-22 involves any new matter.

*Interview Summary*

The undersigned attorney would like to thank the Examiner and her supervisor, Thurman Page, for the courtesies extended during the telephonic interview on May 22, 2007. During the interview, the undersigned attorney, the Examiner and her supervisor, discussed a proposed claim set that Applicants were considering submitting. Upon further consideration, Applicants have decided not to submit the claims discussed during said interview at this time. Again, the undersigned attorney appreciates the time of the Examiner and her supervisor.

*Claim Rejection – 35 U.S.C. Section 102(b)*

Claims 1-16 are rejected under 35 U.S.C. Section 102(b) as being anticipated by Kothrade et al. (U.S. Patent No. 6,284,803). Specifically, the Examiner says that Kothrade et al. teach a pharmaceutical formulation that comprise fenofibrate as the active ingredient, a polymeric binder composed of methyl methacrylate, acrylic acid, cellulose acetate phthalate and hydroxypropylmethylcellulose phthalate and other conventional excipients. The Examiner also says that Kothrade et al. teach that the fenofibrate can be in the form of a molecular dispersion and that the formulation is obtainable by melt extrusion. Applicants respectfully traverse.

In order for a reference to be anticipatory, each and every element of the claimed invention must be disclosed by the reference. Applicants submit that Kothrade et al. does not anticipate the invention as currently claimed. Specifically, claims 1, 3 and 13-15 have been amended to remove the word “derivative” or “fenofibrate”. The term “derivative” was defined in specification as including fenofibrate. As amended, claims 1, 3 and 13-15 encompass fenofibric acid and physiologically acceptable salts thereof. Kothrade et al. simply do not teach formulations containing fenofibric acid or physiologically acceptable salts thereof. Therefore, this rejection has now been rendered moot and should be withdrawn.

*Claim Rejection – 35 U.S.C. Section 103*

The Examiner also rejects claims 1-16 as being obvious under 35 U.S.C. Section 103(a) as being unpatentable over Kothrade et al. According to the Examiner, although Kothrade et al. do not actually exemplify Applicants’ particular formulation, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to combine all of the components described in Kothrade et al. to make a formulation of fenofibrate for pharmaceutical oral administration and that the expected result would be an effective lipid-regulating tablet in dosage form. Applicants respectfully traverse.

As discussed above in connection with the 35 U.S.C. Section 102(b) rejection, Kothrade et al. fail to disclose or suggest formulations comprising fenofibric acid or a physiologically acceptable salt thereof,

methods for oral administration of fenofibric acid or a physiologically acceptable salt thereof, or a dosage form comprising a formulation containing fenofibric acid or a physiologically acceptable salt thereof as recited in the claims. Therefore, in view thereof, Applicants submit that this rejection is now moot and should be withdrawn.

### REQUEST FOR RECONSIDERATION

Reconsideration and withdrawal of all claim rejections are respectfully requested. Applicants believe that the present application is in condition for allowance. Should the Examiner have any questions or would like to discuss any matters in connection with the present application, the Examiner is invited to contact the undersigned. If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account number 04-2223.

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